



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0433; FRL 9998-18]

Pesticides; Interim Process for Evaluating Potential Synergistic Effects of Pesticides during the Registration Process; Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the availability of and soliciting public comment on an interim process it developed to address risk estimate uncertainties associated with U.S. patent assertions of greater than additive effects (GTA effects) in mixtures of pesticide active ingredients for controlling pests (often referred to as “synergy”). EPA developed a process to document, review and, if necessary, revise ecological risk estimates; and invites public comment on this process to obtain and analyze GTA effects data identified in patent assertions.

DATES: Comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number, EPA-HQ-OPP-2017-0433, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on comments or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Edward Odenkirchen, Environmental Fate and Ecological Effects Division (7507P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6449; email address: odenkirchen.edward@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides and/or the potential impacts of pesticide use on listed species and designated critical habitat. Given the broad interest, the Agency has not attempted to identify or describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information

claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, which governs the production, use, distribution, and sale of pesticides. Under FIFRA, pesticides distributed or sold in the United States must first be registered with EPA unless they qualify for an exemption. A cornerstone of the pesticide registration process is the data requirements that applicants must fulfill regarding the pesticide's effects on human health, the environment, and in some cases, its efficacy in controlling pests.

The burden of demonstrating that a product meets the standards for registration rests on the registrant or applicant for registration. To obtain registration, applicants are responsible for citing or generating all data necessary to meet data requirements specified by EPA's regulations at 40 CFR part 158. An ecological risk assessment is one key assessment EPA performs to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. To inform such assessments, EPA requires a range of data in specific categories including: product chemistry, environmental and mammalian toxicity, environmental fate, residue chemistry, reentry exposure, and spray drift.

EPA's historical process for evaluating pesticide ecological risks has relied on toxicity information from studies conducted with single active ingredients based on the lack of information on pesticide interactions and the expectation that they are rare. In 2013, the National

Research Council (NRC) (Ref. 1) stated that toxicological interactions between pesticide active ingredients that produce GTA effects are rare and suggested that the Agency consider pesticide active ingredient interactions when the best available scientific evidence supports the evaluation.

However, in a lawsuit challenging EPA's 2014 decision to register a new pesticide product containing two herbicide active ingredients (Enlist Duo Herbicide) (Ref. 2), the plaintiffs presented evidence – previously unknown to EPA – that the U.S. Patent and Trademark Office (USPTO) had granted a patent for claims that Enlist Duo produced GTA effects towards pest species. EPA subsequently discovered that a number of other registrants were making similar claims of GTA effects towards pest species before the USPTO, but were not disclosing these GTA claims to EPA. Based on the new information regarding the potential synergistic effects on non-target organisms when the two pesticide active ingredients of Enlist Duo Herbicide are applied together, EPA asked the court to remand the Enlist Duo Herbicide registration decision to EPA for consideration of its potential for synergistic effects (Ref.3). Subsequently, in 2016, and 2017, EPA received petitions asking it to require registrants to provide information on potential synergy for consideration in EPA's ecological risk assessments. In addition, subsequent public comments submitted regarding pesticide regulatory decisions continue to include this issue as a concern.

III. Interim Process

The criteria for use of GTA data for patent applications are different than for EPA's quantitative analyses of risk. While the USPTO patent evaluation process uses a standard that the issued assertion must be novel and “non-obvious” (<https://www.uspto.gov/web/offices/pac/mpep/mpep-2100.pdf>), for EPA's quantitative risk assessments, the data must meet the same standards for use of other toxicological data. To

address risk estimate uncertainties associated with patent assertions of GTA effects, EPA has developed an interim process to obtain, analyze, and document patent claims of GTA effects in mixtures of pesticide active ingredients. The purpose of the interim process is to evaluate the utility of collecting and reviewing GTA patent information for use in conducting risk assessments, and to determine if such data, where applicable, affect risk assessments. This process is described in a document titled “Process for Receiving and Evaluating Data Supporting Assertions of Greater than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants” (Ref. 4) and summarized in this unit. The document is available on the Agency’s website: <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical> and in the docket.

Generally, for new chemicals (specifically new conventional pesticide active ingredients) and other new products or other active ingredients for which EPA has specific concerns about the potential for GTA effects, as part of the registration process, EPA will request registrants to provide GTA effect information on approved patents and conduct appropriate statistical analysis of that information using the following steps:

Step 1: Search for and identify granted U.S. patents with applications that made any claims of GTA effects;

Step 2: Conduct a review of patent data for relevance to ecological risk assessment;

Steps 3, Report effects testing data from relevant patents; and

Step 4: Perform a statistical analysis using an EPA-established method to evaluate if observations of GTA effects are statistically significant.

Step 5 is an Agency review of the submitted information from **Steps 1-4**.

Consistent with EPA's review of any scientific data submitted for inclusion in the regulatory process, EPA will review submitted patent searches and relevancy reporting in submissions to ensure that the process is consistent with the Agency interpretation of patent reporting and relevancy review.

EPA has generally been applying this interim process since 2016. EPA's experience with the application of this interim process to date suggests that patent submissions with relevant information that demonstrate a sufficiently large, statistically significant GTA interaction requiring quantitative consideration in ecological risk assessments will likely be rare. More specifically, for the 24 new active ingredient registrations that submitted patent data to date, three contained pertinent information that indicated a need for further testing and none ultimately led to adjustment in the risk assessment. EPA plans to re-evaluate this interim process considering public comment and after it has collected and analyzed more GTA patent information submitted during registrations. Ultimately, EPA plans to look at the results of this process to inform its determination as to whether patent data has utility in EPA's risk assessments. If the interim process demonstrates it does, then EPA plans to continue to request or require registrants provide patent data and follow this process (or an improved process reflecting comments and/or lessons learned). If the process demonstrates that the patent data does not have utility in EPA's risk assessments, EPA plans to communicate that to the public and discontinue this process.

IV. Public Comments Sought

EPA is seeking comment on the interim process for assessing potential GTA effects of pesticides during the registration process. Specifically, EPA solicits comments on the following:

- Are there technical aspects of the interim process that warrant change? If so, what

changes are recommended?

- What aspects of the process could be applied to the evaluation of open literature sources of GTA effects pesticide interactions?

- Should EPA consider standardizing a more detailed search and reporting approach, and how should EPA do that?

- Should EPA continue the evaluation process as described in this document? If so, what performance metrics (*e.g.*, number of evaluations) should EPA consider before deciding the utility of this approach?

- What applicant burden is associated with the activities described in this memorandum, including compiling, analyzing, and submitting the information? Specifically, does an estimate of 80 – 240 hours of burden per applicant cover the respondent burden associated with the interim process?

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. National Research Council (NRC) 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. The National Academies Press, Washington DC.

2. Case Nos. 14-73353, 14-73359, 15-71207, 15-71213 United States Court of Appeals for the Ninth Circuit ID: 9731620, DktEntry: 56-1, Page 1 of 215.

3. Case Nos. 14-73353, 14-73359, 15-71207, 15-71213 United States Court of Appeals for the Ninth Circuit ID: 9770038, DktEntry: 121-1, Page 1 of 12.

4. U.S EPA. Process for Receiving and Evaluation Data Supporting Assertion of Greater than Additive (GTA) Effects in Mixtures of Pesticide Active Ingredients and Associated Guidance for Registrants, August 2019. It is available at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical>.

Authority: 7 U.S.C. 136 *et seq.*

Dated: September 3, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator.

[FR Doc. 2019-19324 Filed: 9/6/2019 8:45 am; Publication Date: 9/9/2019]